

REMARKS

In response to the Office Action dated March 18, 2009, Applicants have amended claims 133, 136, and 140 solely to clarify particular aspects of the invention. Claims 128-132, 134, and 135 have been canceled and no new claims have been added. Support for the amendments may be found throughout the specification and original claims as filed, for example, on page 6, lines 24-29, page 225, lines (5-17), page 226, lines 7-20, and page 243 (18-22). No new matter has been added. The above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application. Following the amendments, claims 133, and 136-143 are pending and under examination. Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks.

INFORMATION DISCLOSURE STATEMENT

The information disclosure statement filed May 31, 2006, allegedly fails to comply with 37 C.F.R. 1.142(b) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 C.F.R. 1.56(c) most knowledgeable about the content of the information of each patent listed that is not in the English language. Specifically, the Examiner contends that no concise explanation has been presented for references AL (WO99/60094) and AO (WO02/07100); thus, the Examiner has not considered these references.

Applicants submit herewith a supplemental IDS, listing reference AA (U.S. Application Number 10/088550; "the `550 application"). Applicants respectfully submit that the `550 application is the U.S. national stage entry of AO (WO02/07100). Applicants further submit that the disclosure of `550 is cumulative to the disclosure of AO (WO02/07100). Regarding AL (WO99/60094), Applicants respectfully submit that the English translation of the abstract, provided on the face of WO99/60094, is a concise explanation of the relevance of the reference. The English translated abstract is provided below for the Examiner's convenience:

“The invention relates to a method for determining the interaction of chemicals with cells in a reactor, e.g. in a fixed-bed reactor or in a fluid-bed reactor. To this end, a signal is measured which is produced by one of the components affected during the interaction. The signal is suited for being detected by a detection system situated outside of the reactor. The component which produces the signal can be the chemical itself, in which case, it can concern the analysis of the pharmacokinetic characteristics of the chemical. An additional possibility relates to the analysis of an influence of the chemical on processes within the cell. A device for carrying out the inventive method comprises a reactor for accommodating cells, a circulation system, control units for monitoring the composition of the medium, a system for gassing the medium, an entry for the chemical and at least one detection system for detecting the interaction.”

Reconsideration of the references and withdrawal of this basis for rejection is respectfully requested.

SPECIFICATION

The Examiner objects to the specification because the formulas on pages 163-166 and 169 allegedly overlay and obscure the text of those pages. Applicants submit herewith, an amended specification for pages 163-169, wherein the formulas do not overlay or obscure the text of those pages. No new matter has been added. Reconsideration and withdrawal of this basis for objection are respectfully requested.

CLAIMS REJECTIONS UNDER 35 U.S.C. §101, FIRST REJECTION

Claims 128-132, 134, and 135 stand rejected under 35 U.S.C. §101 because the claimed invention is allegedly drawn to non-statutory subject matter. Specifically, the Action alleges that the presently claimed process is not directed to a particular machine or apparatus or does not transform an article to a different state or thing, and thus, the presently claimed process is directed to non-statutory subject matter. Applicants respectfully note that claims 128-132, 134, and 135 have been canceled without acquiescing to any ground of rejection. Accordingly, this basis of rejection is now moot. Reconsideration and withdrawal of this basis for objection are respectfully requested.

CLAIMS REJECTIONS UNDER 35 U.S.C. §101, SECOND REJECTION

Claims 128-133 stand rejected under 35 U.S.C. §101 because the claimed invention is allegedly drawn to non-statutory subject matter. Specifically, the Action alleges that the invention fails to produce a useful, concrete, and tangible result, and thus, the presently claimed invention is directed to non-statutory subject matter. As noted above, claims 128-132 have been canceled. Thus, this basis for rejection is moot with regard to those claims.

Applicants respectfully traverse this basis for rejection and submit that the presently claimed invention is statutory subject matter.

The Action alleges that the claims do not require the production of a tangible result in a form that is understandable to the user of the process or apparatus. The Action contends that the rejection could be overcome by amendment of the claims to recite that a result of the process is outputted to a physical memory device, a display, to a user, in a graphical format, or in a user readable format, or by including a physical transformation.

Applicants, without acquiescence and solely in a good faith effort to expedite prosecution, have amended claim 133 to recite “wherein the apparatus further comprises a means for storing the at least one collection of experimental data against the cell.” Support for this amendment can be found throughout the specification as filed, for example, on page 225, lined (5-17) and page 243, lines 18-22, and thus, does not constitute new matter.

Accordingly, Applicants respectfully submit that the presently claimed apparatus produces a tangible real-world result, and thus, comports with the requirements of 35 U.S.C. §101 and is statutory subject matter. Reconsideration and withdrawal of this basis for objection are respectfully requested.

CLAIMS REJECTIONS UNDER 35 U.S.C. §103(A)

Claims 128-133 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Rine et al. (WO98/06874). Specifically, the Action alleges that Rine et al. teach a process and apparatus that collects and stores data from a plurality of cells, said data being reporter signals generated as a response to a stimulation. The Action correctly notes that Rine et al. fail to teach or suggest recording the cell type, stimulus, or cell culture medium.

However, the Action concludes that it would have been obvious for the skilled artisan to include the experimental cell type, culture medium, and stimulus in the recorded profile data to aid in comparisons to other profiles.

Claims 134-137, 140, and 141 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Rine et al. (WO98/06874) in view of Rosenblum (U.S. Patent Application Publication No. 2002/0055935). Specifically, the Action alleges that Rine et al. teach as noted above in the preceding obviousness rejection. The Action correctly notes that Rine et al. fail to teach or suggest a comparison initiated by a requester, consideration of multiple databases for the comparison, provision of the results of the comparison to the requester, or requesting of a comparison via the internet. However, the Action contends that Rosenblum teaches these aspects of the presently claimed invention. Therefore, the Action concludes that it would have been obvious to the skilled artisan to modify the process and apparatus of Rine et al. by the use of the biological database query method and apparatus of Rosenblum.

Claims 138, 139, 142, and 143 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Rine et al. (WO98/06874), in view of Rosenblum (U.S. Patent Application Publication No. 2002/0055935) and Bimson et al. (U.S. Patent Application Publication No. 2001/0034748). Specifically, the Action alleges that Rine et al. and Rosenblum teach as explained in the preceding obviousness rejection. The Action correctly notes that both Rine et al. and Rosenblum fail to teach or suggest providing the result of a search to the service requestor using a format in the extensible markup language (XML). However, the Action concludes that it would have been obvious for the skilled artisan to use XML format to output the search results of Rine et al. in view of Rosenblum.

Applicants respectfully traverse these bases for rejection. As noted above, claims 128-132 have been canceled. Thus, these bases of rejection are moot with regard to those claims.

Applicants respectfully submit that the Action fails to provide a sufficient basis for one having ordinary skill in the art to predictably arrive at the presently claimed invention with any reasonable expectation of success, and thus, the Action fails to establish a *prima facie* case of obviousness against the presently claimed invention. Moreover, the Action fails to establish a *prima facie* case of obviousness against the presently claimed invention because the references do not teach or suggest each and every element of the claims. “To establish a *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Applicants respectfully submit that claims 133, 137, and 140 have been amended, without acquiescence, to recite

“wherein the stimulus response comprises profile data for the cell obtained by monitoring a biological agent or a collection thereof on or in the cell over time, and wherein during the monitoring, the cell is immobilized to a support by a composition comprising a salt, and an actin-like acting substance.”

Support for these amendment can be found through the specification as filed, for example, on page 226, lines 7-20, and page 6, lines 24-29 and thus, does not constitute new matter.

At a minimum, it must be demonstrated that the cited references provide a sufficient basis to predictably arrive at the presently claimed invention, and even assuming, *arguendo*, that the cited references teach each claim feature, the Examiner must provide an explicit, apparent reason to combine these features in the fashion claimed by the Applicant with a reasonable expectation of success. See *KSR v. Teleflex, Inc.*, No. 04-1350 at 4, 14 (U.S. Apr. 30, 2007) (“A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art”). In the instant case, the Action has failed to account for a means for obtaining a stimulus response, wherein the response comprises profile data for the cell obtained by monitoring a biological agent or a collection thereof on or in the cell over time, and wherein during the monitoring, the cell is immobilized to a support by a composition comprising a salt, and an actin-like acting substance, as presently claimed. Thus, the Action fails to provide sufficient rationale for the skilled artisan to arrive at the presently claimed invention with any reasonable expectation of success.

The Action alleges that Rine et al. teach a process and apparatus that collects and stores data from a plurality of cells, said data being reporter signals generated as a response to a stimulation. The Action also correctly notes that Rine et al. fail to teach or suggest recording the cell type, stimulus, or cell culture medium. However, the Action concludes that it would have been obvious for the skilled artisan to include the experimental cell type, culture medium and stimulus in the recorded profile data to aid in comparisons to other profiles, because Rine et al. show comparisons of the determined profiles with other profiles, and knowing what the cell type, culture, and stimulus are, is essential to comparison of the stimulus results with other stimulus results. Applicants respectfully disagree.

Applicants respectfully submit that an important feature of the subject application is related to the Inventors' discovery that immobilizing the cells onto a specific substrate using a composition that comprises a salt, and an actin-like substance and/or the like, allows the claimed apparatus to be used efficiently to produce the digital cell.

Applicants further submit that it is clear from the as-filed specification and the art, that as of the priority date of the subject application it was not possible to effectively create a digital cell due to the fact that it was not possible to maintain a plurality of cells under a constant environment, which thus rendered the experimental conditions, such as transfection, unreliable (See, for example, page 243, line 29 to page 244, line 1 of the as-filed specification). In this regard, the unreliable experimental conditions resulted in a lack of significance between accumulated results of different experiments (See, for example, page 244, lines 2-3 of the specification as filed).

Moreover, while array technologies have been known since the priority date of the subject application, especially in the field of drug screening (See, for example, page 5, lines 6-22 of the specification as filed), no technique had been provided wherein the information about a particular cell could be provided with any reliable degree of accuracy (See, for example, page 5, lines 24-30 of the specification as filed).

Thus, one having ordinary skill in the art would appreciate that the presently claimed invention, which comprises the immobilization of cells onto a specific substrate using a composition that comprises a salt, and an actin-like substance, provides an advantageous

apparatus that can be effectively used to produce a digital cell (e.g., claim 133). In this regard, Example 1 of the subject application shows a comparison of the transfection of particular cells, wherein said cells were either immobilized to a support by either various actin-like acting substances or by using gelatin as a control. Applicants submit that the results from Example 1 show:

“As can be seen from the results, whereas transfection was not very successful in a system using gelatin, transfection took place to a significant level in systems using fibronectin, ProNectin (i.e., actin-like acting substances; emphasis added) ... [t]herefore, it was demonstrated that these molecules significantly increased transfection efficiency.” (See, for example, page 260, line 26 to page 261, line 4 of the specification as filed).

In addition, the subject application discloses that the immobilization technique of the presently claimed invention is the first system that “can increase transfection efficiency for substantially all cells (emphasis added) and can provide practicable transfection to all cells. ... As can be seen from the results of Figure 6, when coating was provided, contamination was reduced as compared with when coating was not provided ...”(See, for example, page 263, lines 7-20; emphasis added).

Accordingly, in view of the above effects achieved using the presently claimed immobilization features, an advantageous configuration of a digital cell is produced. For example, the as-filed specification states:

“With this technique, it will be possible to achieve high-throughput studies (emphasis added) using solid phase transfection, such as the elucidation of the genetic mechanism underpinning the differentiation of pluripotent stem cells. The detailed mechanism of the solid phase transfection as well as methodologies for the use of this technology for high throughput, real time gene expression monitoring can be applied for various purposes.” (See, for example, page 276, line 28 to page 277, line 5; emphasis added).

In contrast to the presently claimed invention, Rine et al. fail to teach or even remotely suggest the feature that the immobilization of the cells to a support is carried out by using a “composition comprising a salt, and an actin-like acting substance,” as presently claimed. Specifically, Rine et al. merely disclose a silicon-based wafer or the like as a solid support,

wherein the support is not coated with a composition comprising a salt, and an actin-like acting substance, as presently claimed. Rine et al. teach:

“[T]he stimulated physical matrix 310 comprises an ordered array of units having X and Y coordinates ... [T]he units are generally a region of a solid substrate such as a two-dimensional portion of the surface of a silicon-based wafer, a well of a microtiter, etc...” (See, for example, page 4, lines 16-20 of Rine et al.).

Applicants respectfully submit that Rine et al. fail to disclose or suggest any type of apparatus, support, or composition that would lead the skilled artisan to arrive at the presently claimed invention with any reasonable expectation of success. In addition, Rine et al. would have no expectation of success in achieving the unexpected and advantageous results provided by the presently claimed invention. Moreover, neither Rosenblum, nor Bimson et al. remedy the insufficiencies of Rine et al., and thus, in view of the rationale provided in the instant Action, the skilled artisan would not be expected to contrive the presently claimed invention with any reasonable expectation of success.

In regard to the rejection of claims 134-137, 140, and 141 over Rine et al. in view of Rosenblum, the Action concludes that it would have been obvious to the skilled artisan to modify the process and apparatus of Rine et al. by the use of the biological database query method and apparatus of Rosenblum, because Rosenblum shows how access to biological databases by requester may be performed conveniently via the internet. Applicants respectfully disagree and submit that even if the skilled artisan would combine the references as suggested by the Examiner, he would have no reasonable expectation of success in arriving at the presently claimed invention. Applicants respectfully submit that neither Rine et al. nor Rosenblum teach, suggest or provide any rationale for the immobilization of cells to a support using a composition comprising a salt and an actin-like acting substance, as presently claimed; thus, the Action fails to establish a *prima facie* case of obviousness against the presently claimed invention.

In regard to the rejection of claims 138, 139, 142, and 143 over Rine et al. in view of Rosenblum and Bimson et al., the Action concludes that it would have been obvious to the skilled artisan it would have been obvious for the skilled artisan to use XML format to output the search results of Rine et al. in view of Rosenblum, because Bimson et al. Bimson et al. teach

the use of XML formats as a known and useful format for search results. Applicants respectfully disagree and submit that even if the skilled artisan would combine the references as suggested by the Examiner, he would have no reasonable expectation of success in arriving at the presently claimed invention. Applicants respectfully submit that neither Rine et al., Rosenblum, nor Bimson et al. teach, suggest or provide any rationale for the immobilization of cells to a support using a composition comprising a salt and an actin-like acting substance, as presently claimed; thus, the Action fails to establish a *prima facie* case of obviousness against the presently claimed invention.

Accordingly, Applicants respectfully submit that the Action fails to establish a *prima facie* case of obviousness against the presently claimed invention. Reconsideration and withdrawal of these bases for rejection is respectfully requested.

NON-STATUTORY OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 128-133 stand provisionally rejected under the judicially created doctrine of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 92, 84-87, and 90 of co-pending U.S. Patent Application No. 11/630,814. The Examiner contends that although the claims are not identical, they are not patentably distinct from each other because the method of making a digital cell database of the copending claims comprises the same steps as the instant method of making a digital cell. Applicants respectfully submit that claims 128-132 have been canceled. Thus, this basis for rejection is moot with regard to those claims.

Without acquiescing to the rejection, Applicants submit herewith a terminal disclaimer for claim 133 over co-pending U.S. Patent Application No. 11/630,814. Reconsideration and withdrawal of this basis for rejection is respectfully requested.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Application No. 10/562,469
Reply to Office Action dated March 18, 2009

All of the claims remaining in the application are now believed to be allowable.
Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,
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